DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 8, 2015

Invado Pharmaceuticals LLC
Mr. Edward Kobus
President
25 Ravenna Drive
Pomona, New York 10970

Re: K140905
Trade/Device Name: DermaFINE Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 24, 2015
Received: April 29, 2015

Dear Mr. Kobus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K140905

Device Name
DermaFINE Wound Dressing

Indications for Use *(Describe)*
Rx Indications for Use: DermaFINE Wound Dressing is indicated for topical use in the management of full and partial thickness wounds including dermal ulcers, leg ulcers, superficial wounds, first and second degree burns and donor sites to include:

Radiation Dermatitis
Various types of dermatoses
Atopic dermatitis
Allergic contact dermatitis
Dry waxy skin

by maintaining a moist wound and skin environment.

OTC Indications for Use: DermaFINE Wound Dressing Emulsion is indicated for the management of minor cuts, minor burns, and minor lacerations by maintaining a moist wound and skin environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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Invado Pharmaceuticals LLC
25 Ravenna Drive
Pomona, New York 10970
K140905

## 510(k) Summary

Summary Information:

Submitters Name and Address: Invado Pharmaceuticals LLC
25 Ravenna Drive
Pomona, New York 10970

Contact Person: Edward Kobus
President
Phone: 866-963-8881
E-Mail: ekobus@invadopharma.com

Date of Summary Preparation: May 8, 2015

Name of Device:

Proprietary: DermaFine Wound Dressing Emulsion for Topical Application
Common: Dressing, Wound, Drug
Classification Name: Dressing Wound Drug

Medical Device Classification: Unclassified

Product Code: FRO

Identification of predicate devices to which substantial equivalence is being claimed:

| | | |
|---|---|---|
| SonaFine Wound Dressing | Stratus Pharmaceutical | K110172 (Principal Predicate) |
| MimyX Cream | Stiefel Laboratories | K041342 |
| PruMyx Cream | PruGen Pharmaceutical | K082089 |

Description of the Device: DermaFINE Wound Dressing is a preserved emulsion intended to be used as a topically applied preparation to breached and intact skin and is provided in a patient ready, 28 gram (one (1) ounce), 45 gram and 90 gram collapsible tube.

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K140905

Intended use of the Device: DermaFINE Wound dressing provides a moist wound environment. The dressing contains methyl paraben, potassium sorbate and propyl paraben which act as preservatives to inhibit microbial colonization within the dressing.

Rx - DermaFINE Wound Dressing is useful in the management of full and partial thickness wounds including dermal ulcers, leg ulcers, superficial wounds, first and second degree burns and donor sites to include:

Radiation Dermatitis
Various types of dermatoses
Atopic dermatitis
Allergic contact dermatitis
Dry waxy skin

by maintaining a moist wound and skin environment.

OTC – DermaFINE Wound Dressing is indicated for the management of minor cuts, minor burns, and minor lacerations.

Technology Characteristics: This particular, preserved, formulation does not affect the intended use or alter the fundamental scientific technology of the device. DermaFine Wound Dressing contains the same chemical components as the designated predicate as provided in the Device Comparison Table provided below.

## Device Comparison Table

| Parameters | DermaFINE Wound Dressing K140905 | SonaFINE K110172 |
|---|---|---|
| Indications for use | Rx - DermaFINE Wound Dressing is indicated for topical use in the management of full and partial thickness wounds including dermal ulcers, leg ulcers, superficial wounds, first and second degree burns and donor sites to include:<br><br>Radiation Dermatitis<br>Various types of dermatoses<br>Atopic dermatitis<br>Allergic contact dermatitis<br>Dry waxy skin<br><br>OTC - DermaFINE Wound Dressing is indicated for the management of minor cuts, minor burns, and minor lacerations | Rx - SonaFINE Wound Dressing is indicated for topical use in the management of full and partial thickness wounds including dermal ulcers, leg ulcers, superficial wounds, first and second degree burns and donor sites to include:<br><br>Radiation Dermatitis<br>Various types of dermatoses<br>Atopic dermatitis<br>Allergic contact dermatitis<br>Dry waxy skin<br><br>OTC – SonaFINE Wound Dressing is indicated for the management of minor cuts, minor burns, and minor lacerations. |

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| Product Code | FRO | FRO |
|---|---|---|
| Rx | Yes | Yes |
| OTC | Yes | Yes |
| Product Description | Emulsion | Emulsion |
| Preserved | Yes | Yes |
| Formulation | purified water,<br>light mineral oil,<br>ethylene glycol monostearate,<br>stearic acid,<br>propylene glycol,<br>paraffin wax,<br>squalane,<br>avocado oil,<br>triethanolamine alginate,<br>cetyl palmitate,<br>methylparaben (sodium salt),<br>propylparaben (sodium salt),<br>fragrance | purified water,<br>light mineral oil,<br>ethylene glycol monostearate,<br>stearic acid,<br>propylene glycol,<br>paraffin wax,<br>squalane,<br>avocado oil,<br>triethanolamine alginate<br>cetyl palmitate,<br>methylparaben (sodium salt),<br>propylparaben (sodium salt), |
| Dermal Irritant | No | No |
| Cytotoxic | No | No |
| Dermal Sensitizer | No | No |
| Product Classification | Unclassified | Unclassified |

Non-Clinical Performance Data: DermaFINE Wound Dressing has been evaluated in accordance with Part 10-993 of the International Standard Organization (ISO). Standard tests which include:

- Agar Overlay (direct contact) Cytotoxicity testing indicated a grade 0 cytotoxic grade.
- Primary Skin Irritation ISO Direct Contact indicated no erythema, no edema
- Kligman Maximization Test ISO Direct Contact indicated Grade 1, weak allergenic potential.
- Antimicrobial Preservatives Effectiveness Test

DermaFINE Wound Dressing has not been studied in a clinical setting.

End of Summary